score distributions and indices of reliability and validity. **RESULTS:** The literature review and input from patients indicates that HS is associated with a range of symptoms (e.g., pain, drainage, itchiness) and impacts (e.g., difficulty with movement and interference with sexual activities). These concepts were organized into a conceptual model to facilitate the construction of the questionnaires. Results from the cognitive interviews indicated that both the HSSA and HSIA are easily understood by patients and characterize their condition well. Forty subjects completed the observational study (females = 58%; Caucasian = 65%; and age [mean] = 41 years). The HSIA and HSSA scores were found to perform well psychometrically, with strong evidence of test-retest (ICC=0.92 and 0.80, respectively) and internal consistency (α=0.97 and 0.96, respectively) reliability and known groups (P<0.001 and P<0.006, respectively) and construct-related validity (via correlations between the target measures and other, concurrently administered tools). **CONCLUSIONS:** There is robust evidence supporting the HSIA and HSSA as content valid and psychometrically sound questionnaires for assessing symptoms and impacts in patients with HS.

PSS30

SENSITIVITY OF FUNCTIONAL READING INDEPENDENCE (FRI) INDEX TO CHANGE IN SIZE OF GEOGRAPHIC ATROPHY

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OBJECTIVES: Visual acuity does not fully capture the effect of geographic atrophy (GA), secondary to age-related macular degeneration, on visual function. The Functional Reading Independence (FRI) Index is a 7-item patient-reported measure developed for use in GA trials. This study examined the sensitivity of the FRI Index to change in GA lesion size. **METHODS:** Post hoc analyses were conducted with data from MAHALO, a phase 2 study of lampalizumab, a complement factor monoclonal antibody fragment, for treatment of GA. For each reading activity performed in the past 7 days (e.g., writing checks or reading medicine labels), patients were asked the extent to which they required vision aids, adjustments in the activity, or help from another person. The FRI Index yields continuous mean scores (range 1-4) and ordinal level scores (from Level 1=Unable to do to Level 4=Totally Independent). Analysis of covariance compared mean changes in FRI Index scores stratified by more (≥0.94mm2/yr) vs less (<0.94mm2/yr) GA lesion growth. **RESULTS:** At 18 months, the mean change in FRI Index score (SD) from baseline for patients with more lesion size growth was -0.3 (0.5; n=13) vs -0.1 (0.7; n=62) for patients with less growth (P=0.02). For patients with more growth, 36% declined ≥1 FRI Level vs 15% for less growth. Excluding patients at FRI Level 1 at baseline, 41% of patients with more growth (N=54) declined > 1 FRI Level vs 18% with less growth (N=11). **CONCLUSIONS:** In MAHALO, the change in mean FRI Index score of 0.2 differentiated patients with more vs less growth of GA lesion size. FRI level scores were also sensitive to GA lesion growth. These results provide evidence that patient-reported functional reading independence as measured by the FRI Index is linked to GA lesion growth, an objective clinical measure of disease progression.

PSS31

DEMONSTRATING CONCEPTUAL EQUIVALENCE: TRANSLATION OF THE URTICARIA ACTIVITY AND IMPACT MEASURE (U-AIM) FROM ENGLISH INTO SPANISH

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OBJECTIVES: Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinational research studies. The Urticaria Activity and Impact Measure (U-AIM) is a disease specific tool developed in English to assess the impact of chronic urticaria from the patient's viewpoint. The objective of this work was to translate and linguistically validate the U-AIM from English to Spanish for use in the US. **METHODS:** The U-AIM was translated into universal Spanish according to industry standard methodology. After the translation was completed, five Spanish-speaking patients in the US diagnosed with chronic idiopathic urticaria completed the translated questionnaire and participated in a cognitive debriefing interview. Interviews were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity of the U-AIM was maintained for the Spanish version. **RESULTS:** Of the five patients (40% male), the mean age of four was 37 years [one patient did not report his age]. All U-AIM items were well understood and proved relevant to the patients in this sample. Of interest, terms such as, "urticaria," "hives," "angioedema" and "rapid swelling" were clearly understood as intended. **CONCLUSIONS:** The results indicate that the Spanish version of the U-AIM translation is conceptually equivalent to the English source version and easily understood by the target population in the US. We consider the translation to be acceptable for PRO assessment in research and clinical practice. Future research could include testing of the questionnaire with patients in other Spanish-speaking countries to confirm its acceptability beyond the US.

PSS32

PATIENT REPORTED OUTCOMES IN GLAUCOMA A SYSTEMATIC REVIEW

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OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). Glaucoma is a chronic disease with high importance for patient HRQoL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with Glaucoma. **METHODS:** A systematic literature search for Glaucoma trials with PROs endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar and Cochrane. Data was collected for the study size, interventions, year, PRO instrument and results for PROs. Analysis for conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. **RESULTS:** 31 studies with a total of 9819 patients were identified. In these studies there were eleven different PROs instruments were identified that were Glaucoma health perception index, Glaucoma quality of life questionnaire (Glau-QoL), Glaucoma utility index, Impact of vision impairment, Low vision quality of life questionnaire, National eye institute visual function index-19 items, National eye institute visual function index-51 items, Nursing home vision quality of life questionnaire, Quality of life and visual function questionnaire, Vision core module 1, and Vision quality of life index. The most commonly used instruments were Impact of vision impairment (used in 7 studies) and Low vision quality of life questionnaire (used in 4 studies). **CONCLUSIONS:** Patients with glaucoma have significant impairment in their QoL, hence collection of such data is important for new medical products. PRO instruments such as Impact of vision impairment and Low vision quality of life questionnaire have been commonly used to generate evidence to show which therapies improve patient QoL.

PSS33

BENEFITS OF PATIENT-REPORTED OUTCOMES IN DERMATOLOGY DRUG DEVELOPMENT

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OBJECTIVES: A recent systematic literature review of randomized controlled dermatology-related trials showed that patient-reported efficacy outcomes (PROs) were mentioned in some form in only 25.6% of 125 trials between 1994 and 2001. Our research aimed to characterize the benefits of PROs in drug development in dermatology from the patient, prescriber, regulator, payer, and manufacturer perspectives using a case study approach. The case studies were identified based on the use of PROs in pivotal clinical trials for the product. **METHODS:** A targeted literature review was conducted in PubMed from 2004 to 2014 for six products (Atopiclair for atopic dermatitis, botulinum toxin type A for hyperhidrosis, calcipotriol plus betamethasone dipropionate gel for scalp psoriasis, pimecrolimus and tacrolimus for atopic dermatitis, and ustekinumab for psoriasis. Regulatory and health technology agency websites and publications were searched for documentation of PRO label claims and mentions. **RESULTS:** For patients, inclusion of PROs ensured the full benefit of the product was demonstrated, including improvement in symptoms, quality of life, and/or treatment satisfaction. For prescribers, comparative trials reported PRO data information on each product's benefits and risks and also which product was superior from the patient perspective. For regulators, for all except one of the six products, PROs were included in the product label. For payers, utility values based on PROs were used in cost-effectiveness evaluations for three of the six products. For the manufacturer, the PRO data generated label claims and many publications that allowed extensive public dissemination of product benefits. **CONCLUSIONS:** Patient-reported assessment of the treatment impact on disease during drug development has many benefits for all stakeholders.

PSS34

RASCH ANALYSIS OF A NEW PATIENT REPORTED OUTCOME MEASURE FOR PSORIASIS TREATMENT (PROMPT)

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OBJECTIVES: A draft patient-reported outcome measure for psoriasis treatment (PROMPT) was developed through patient interviews and comprised 91 items across seven core domains. This study aimed to evaluate the scaling properties and construct validity of the draft measure using the Rasch measurement model. **METHODS:** Patients with chronic plaque psoriasis were identified and recruited according to pre-defined inclusion and exclusion criteria through psoriasis-specific secondary care clinics in the United Kingdom and two national patient organizations. Patients completed the draft measure at two time points, 14 days apart. Respondents with ≥40% of missing data were removed from the final analyses. Data from each sub-scale were analyzed separately using RUMM2030 software to explore Rasch model fit, item difficulty, local dependence, item category thresholds, and differential item functioning (DIF) by age and gender. Where necessary, items were removed individually and the scale iteratively reassessed for fit and unidimensionality. **RESULTS:** A sample of n=209 patients with chronic plaque psoriasis completed the draft measure. Initial fit to the model was poor; disordered category thresholds were identified for items in all scales. Post-hocre-scoring from a 5-point Likert scale to a 3-point Likert scale improved model fit. Items which showed local dependence were removed in context of qualitative findings. Following removal of 11 items, all 7 scales demonstrated acceptable fit with the Rasch model (Chi Sq = 0.09 to 0.2) There was no evidence of DIF by age and gender. **CONCLUSIONS:** The new measure, PROMPT, comprised 80 items in 6 independent, unidimensional scales, free from age or gender bias, with acceptable fit to the Rasch model. As such, the measure is considered to show initial promise for use with patients with chronic plaque psoriasis in a clinical setting. The psychometric properties and scoring of the measure should be explored further and confirmed in future studies.

PSS35

CONTENT DEVELOPMENT AND REFINEMENT FOR A NEW PATIENT REPORTED OUTCOME MEASURE FOR PSORIASIS TREATMENT (PROMPT)

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